DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

DEC 26 2000

Warning Letter

Certified Mail
Return Receipt Requested

Mr. Stan Cipkowski
Chief Executive Officer
American Bio Medica Corporation
300 Fairview Avenue
Hudson, New York 12534

Dear Mr. Cipkowski:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed a press release distributed by American Bio Medica on September 20, 2000. In the press release, published on the Internet at http://biz.yahoo.com/bw/000920/ny_america.html, you stated that "it is extremely important to note that our Rapid Drug Screen will detect Ecstasy." You also stated that "the Company has applied to the FDA for approval for sales to consumers and until such time that approval is received, they can still get quick results by having their doctor administer the Rapid Drug Screen."

The Rapid Drug Screen 5-Panel Test with Methamphetamine (K984525) was cleared by CDRH on December 21, 1999, for the following intended use: The Rapid Drug Screen 5-Panel test with Methamphetamine is used for the qualitative detection of the following substances in human urine: d-Amphetamine, Benzoylecgonine, Cannabinoids, Opiates, and Methamphetamines. There is no mention of a claim to detect Ecstasy (Methylenedioxymethamphetamine).

Our records do not show that you obtained marketing clearance before you began offering your product for sale for the detection of Ecstasy. We believe that this claim is significant. The kind of information you need to submit in order to obtain this clearance can be obtained by contacting the Division of Clinical Laboratory Devices at 301-594-3084. The FDA will evaluate this information and decide whether your product may be legally marketed.

Because you do not have marketing clearance from FDA, marketing your product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete you correction. Please direct you response to Betty Collins, Chief, In Vitro Diagnostic Devices Branch, 2094 Gaither Road, HFA-321, Rockville, Maryland 20850.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Betty Collins at 301-594-4588.

Sincerely yours,

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health